IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: James Keck *et al.*	Art Unit	: 1633
Serial No.	: 09/601,997	Examiner	: Janet L. Epps-Ford
Filed	: December 15, 2000	Conf. No.	: 5984
Cust. No.	: 20985		
Title	: NON-BACTERIAL CLONING IN DELIVERY AND EXPRESSION OF NUCLEIC ACIDS		

Mail Stop Petition
Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

SECOND PETITION PURSUANT TO 37 C.F.R. §1.181

Dear Sir:

Applicant hereby submits a second Petition pursuant to 37 C.F.R. §1.181 (hereinafter, "Second Petition"), for reconsideration and removal of the finality of the Office Action mailed March 26, 2007 (hereinafter, "Recent Final Office Action"), in connection with the above-captioned application. This Petition is filed within two months of the mailing of the Recent Final Office Action. Enclosed herewith is a check including the fee for this Petition, as prescribed in 37 C.F.R. §1.17(h). If the accompanying fee is incorrect or missing, or should additional fees be required, authorization is hereby given to charge Deposit Account No. 06-1050.

The Second Petition also is responsive to a second *PETITION DECISION* mailed March 16, 2007 (hereinafter, "Second Decision"), in connection with the above-captioned application. The Second Decision issued further to: (1) an initial *PETITION UNDER 37 C.F.R. §1.181* (hereinafter, "First Petition"), filed October 30, 2006, for removal of the finality of a previous Final Office Action mailed October 18, 2006 (hereinafter, "Previous Final Office Action"); (2) a Decision mailed December 20, 2006 (hereinafter, "First Decision"), granting the Petition in part on grounds that the final Office Action was "incomplete," but denying it in part on grounds that the finality was proper; and (3) a renewed Petition filed January 16, 2007, (hereinafter,

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Stephanie Seidman

"Renewed Petition") for reconsideration of the Decision, in which Applicant again urged that the finality of the previous Final Office Action was improper.

In the Second Decision mailed March 16, 2007, the Director states that the Renewed Petition filed by Applicant is premature because the Previous Final Office Action mailed October 18, 2006, was withdrawn before the Renewed Petition was filed. The Director further states that, although Applicant's arguments set forth in the Renewed Petition for removal of finality "have some merit" and are expected to be evaluated by the Examiner when issuing the next Office Action, until such time as the next Office Action issues and is deemed Final, no requests for removal of finality can be considered. The instant Second Petition requesting reconsideration and removal of finality, therefore, is being submitted after issuance of the Recent Final Office Action on March 26, 2007.

FINAL OFFICE ACTION MAILED MARCH 26, 2007

A Recent Final Office Action issued March 26, 2007, in connection with the above-captioned application. The Recent Final Office Action essentially mirrors the Previous Final Office Action mailed October 18, 2006, in which the pending claims were rejected on various grounds under 35 U.S.C. §112, second paragraph, as being indefinite. In the Recent Final Office Action, the Examiner states that the Action, which sets forth the same or similar grounds of rejection as the Previous Final Office Action, is deemed final regardless of Applicant's two Petitions under 37 C.F.R. §1.181 for removal of finality of the Previous Final Office Action mailed October 18, 2006 (the First Petition and the Renewed Petition, as discussed under (1) and (3), respectively). The Examiner further states that the finality is maintained in the Recent Final Office Action because the decisions on both Petitions allegedly rejected Applicant's arguments regarding improper new grounds of rejection on the premise that the Examiner "merely expanded on the [previous] rationale" for finding the claims indefinite.

To begin with, Applicant respectfully disagrees with the Examiner's characterization of the decisions on Applicant's two Petitions. While the decision on the First Petition noted that the finality of the Previous Final Office Action mailed October 18, 2006, appears to be proper, **the decision on Applicant's *Renewed* Petition clearly stated that Applicant's arguments for removal of finality, based on a new ground of rejection not necessitated by amendment,**

"have some merit and it is expected that the Examiner will reevaluate whether to maintain any rejections..." Contrary to the Examiner's characterization, the latter Second Decision, mailed March 16, 2007, was granted in part only to the extent that the Previous Final Office Action was withdrawn and no new Final Office Action had issued at the time Applicant's Renewed Petition was filed on January 16, 2007. The Second Decision, namely, to "grant-in-part" Applicant's Renewed Petition, was not based on a consideration of the propriety of finality of the Office Action. In fact, as discussed, to the extent the Second Decision comments on Applicant's arguments in support of its impropriety, the comments note that Applicant's arguments "have some merit" and it is expected that the Examiner will evaluate them. It respectfully is submitted that the Examiner appears not to have done so.

By filing this Second Petition, Applicant hereby respectfully requests reconsideration and removal of the finality of the Recent Final Office Action mailed March 26, 2007. Applicant respectfully submits that, for at least the reason set forth below, the finality of the Recent Final Office Action is improper because it sets forth a new ground of rejection not necessitated by amendment.

REJECTION THAT THERE IS NO MENTION OF A "CONTROL, UNTRANSFECTED HOST CELL" FOR ANALYZING CHANGES IN PHENOTYPE.

In the Recent Fiinal Office Action mailed March 26, 2007, the Examiner alleges that Claim 58 and its dependents are incomplete because there is no mention of a control, untransfected host cell for comparison with the transfected cell when analyzing changes in phenotype in the transfected cell.

Applicant respectfully submits that the above ground of rejection of Claim 58 and dependents could have been applied in a previous Office Action mailed October 20, 2005, or indeed in any one of several non-final earlier Office Actions that issued in connection with the above-captioned application including, for example, the Office Action mailed January 9, 2003, the Office Action mailed April 20, 2004, and the Office Action mailed February 3, 2005. As discussed in the First Petition mailed October 30, 2006, the Renewed Petition mailed January 16, 2007, and herein, **the claims never mentioned a control, and have never been rejected on this**

basis. Hence the assertion that the claims fail to recite a control is a new ground of rejection not necessitated by amendment of the claims.

(A) Claim 58 as pending at the time the previous Office Action was mailed (October 20, 2005)

For example, at the time that the previous Office was mailed (October 20, 2005), Claim 58 recited:

> A high-throughput method of assigning a function associated with a product coded for by a sample nucleic acid sequence in a target nucleic acid molecule, said method comprising:
>
> a) without any intervening bacterial cloning steps and without any conformational modeling of mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence, delivering into and amplifying and expressing a plurality of members of an oligonucleotide family as individual transcription products in a plurality of recombinant non-bacterial host cells comprising the target nucleic acid molecule that comprises the sample nucleic acid sequence, whereby the method is high-throughput, wherein:
>
> the members of the oligonucleotide family comprise a plurality of nucleic acids each encoding a transcription product comprising a sequence that is complementary to a sequence contained in the mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence;
>
> the plurality of members of the oligonucleotide family are introduced into expression vectors, which are introduced into the host cells, wherein the expression vectors comprise:
>
> double-stranded DNA, comprising:
>
> a sense strand and an antisense strand, wherein the sense strand codes for an antisense strand that, when expressed as RNA, binds to an mRNA sequence transcribed from the target nucleic acid sequence so that expression of a product from the target nucleic acid is inhibited; and
>
> means for determining directionality of expression, wherein the product is associated with at least one phenotypic property of a host cell containing the mRNA sequence; and wherein the expression vector is for expression in non-bacterial host cells;
>
> the coding sequences for each individual transcription product encodes an antisense nucleic acid that, when expressed as RNA, binds to the mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence; and

expression of one or more of the individual transcription products inhibits production of a product of the mRNA; and

b) **in the resulting host cells, analyzing changes in phenotype** to thereby assign a function associated with the product encoded by the sample nucleic acid sequence in the target nucleic acid molecule. (emphasis added).

(B) Claim 58 as pending at the time the instant final Office Action was mailed (October 18, 2006) (amended portions responsive to previous Office Action of October 20, 2005, indicated in underline (additions) and strikeout (deletions))

Claim 58 as presently pending recites:

A high-throughput method of assigning a function associated with a product coded for by a sample nucleic acid sequence in a target nucleic acid molecule, said method comprising:

a) without any intervening bacterial cloning steps and without any conformational modeling of mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence, delivering into and amplifying and expressing a plurality of members of an oligonucleotide family as individual transcription products in a plurality of recombinant non-bacterial host cells comprising the target nucleic acid molecule that comprises the sample nucleic acid sequence, whereby the method is high-throughput, wherein:

the plurality of members of the oligonucleotide family are introduced into expression vectors, which are introduced into the host cells, wherein the expression vectors comprise:

double-stranded DNA, comprising:

a sense strand and an antisense strand, wherein the sense strand codes for an antisense strand that, when expressed as RNA, binds to an mRNA sequence transcribed from the target nucleic acid sequence so that expression of a product from the target nucleic acid is inhibited; and

means for determining directionality of expression, wherein the product is associated with at least one phenotypic property of a host cell containing the mRNA sequence; and wherein the expression vector is for expression in non-bacterial host cells;

the coding ~~sequences~~ sequence for each individual transcription product encodes an antisense nucleic acid that[[,]] ~~when expressed as RNA,~~ binds to the mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence; and

expression of one or more of the individual transcription products inhibits production of a product of the mRNA; and

b) **in the resulting host cells, analyzing changes in phenotype** to thereby assign a function associated with the product encoded by the sample nucleic acid sequence in the target nucleic acid molecule. (emphasis added)

As the emphasized (bold) sections of Claim 58 as recited in (A) and (B) above show, the step of analyzing changes in phenotype has not been amended responsive to the previous Office Action. In fact, at no point during prosecution of this application was the above phrase "analyzing changes in phenotype" (in the transfected host cells produced by the method) amended responsive to an Office Action and/or rejections cited therein. Therefore, the rejection that the claims are indefinite for failing to recite a control could have been applied in the previous Office Action mailed October 20, 2005, or indeed in any of the non-final Office Actions that have issued in this case. The claims however have never been rejected on this basis prior to the Previous Final Office Action mailed October 18, 2006, and the Recent Final Office Action mailed March 26, 2007.

Because the step of "analyzing changes in phenotype" was not amended responsive to the previous Office Action, and in fact always has been recited as such without mention of a control, therefore the rejection of indefiniteness for failing to recite a control was not necessitated by amendment and could have been applied in the previous Office Action or in any one of a number of Office Actions prior to the Previous Final Office Action and the instant Recent Final Office Action. Applicant therefore respectfully submits that the basis of indefiniteness for failure to recite a control is a new ground of rejection that renders the finality of the instant Office Action improper.

Failure to withdraw the finality of the instant Recent Final Office Action denies the Applicant the right to amend the claims, if needed, and/or provide arguments to overcome these rejections, not previously of record during the prosecution of this application. **For example, prior to the Previous Final Office Action and the instant Recent Final Office Action, Applicant has never been granted the opportunity to address the alleged indefiniteness of the claims because the step of "analyzing phenotypic changes" must (allegedly) recite a comparison against a control.** Applicant therefore respectfully requests reconsideration and removal of the finality of the Office Action mailed March 26, 2007.

In light of the above remarks, reconsideration and removal of the finality of the Office Action mailed March 26, 2007, are respectfully requested. Any fee for filing this request for reconsideration or in connection with this application during its pendency can be charged to Deposit Account No. 06-1050.

Respectfully submitted,
FISH & RICHARDSON P.C.

By: _____
Stephanie L. Seidman
Registration No. 33,779

Attorney Dkt. No. 21121-007US1/2307US

Address all correspondence to:
Stephanie L. Seidman, Esq.
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, California 92130
Telephone: (858) 678-5070
Facsimile: (202) 626-7796
EMAIL: seidman@fr.com

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TRANSMITTAL LETTER

Dear Sir:

Transmitted herewith is a Petition pursuant to 37 C.F.R. §1.181 with a check for the requisite fee ($130.00) for filing in connection with the above-identified application.

☒ The Commissioner is hereby authorized to charge the fee for the extension of time and any other fee that may be due in connection with this and the attached papers or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

Stephanie Seidman
Reg. No. 33,779

Attorney Docket No. 21121-007US1/2307US
Address all correspondence to:
Stephanie L. Seidman
Fish & Richardson P.C.
12390 El Camino Real
San Diego, California 92130
Telephone: (858) 678-5070
Facsimile: (202) 626-7796
email: seidman@fr.com

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Fish & Richardson P.C.
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San Diego, California 92130
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Facsimile: (202) 626-7796
email: seidman@fr.com

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